AUG 2 7 2004

K040315

MCI Clenching Inhibitor

510(k) Summary of Safety and Effectiveness

Device Generic Name
Occlusal Stent

Device Trade Name
MCI Clenching Inhibitor

Regulation Number and Name
21 CFR 872.5570 Device, Jaw Positioning

Product Code
LQZ

Panel Code
Dental

Applicant Name and Address
MCI-Myohealth Systems
6B Inga Parade, Mt. Martha VIC 3934
AUSTRALIA

Contact Information
Dave Balding
Consultant
26552 Tampico Place
Mission Viejo CA 92691
USA
Phone: (949) 412-0619 or (949) 916-2663
Fax: (949) 916-2663

Device Description

The Myohealth Clenching Inhibitor disrupts the activity of the pericranial musculature by providing contact between the anterior (incisor) teeth and preventing contact of opposing rearward teeth. The modified dental contact provided by this intraoral device modifies the neuromuscular response of the body to reduce contraction of the pericranial musculature and the associated bruxism and temporal mandibular disorders.

The MCI is an anterior device custom fabricated for each patient. The Myohealth Clenching Inhibitor is intended for treating conditions diagnosed by medical professionals.

The MCI Clenching Inhibitor is designed to span 6 teeth, from upper cuspid to cuspid. The larger size of the MCI greatly reduces the risk of inhalation or swallowing this appliance. The MCI Clenching Inhibitor has a thermoplastic lining. This lining ensures excellent long term retention.

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Comparison to Predicate Device

Attribute	Myohealth Clenching Inhibitor	Predicate (NTI Clenching Suppression System, K981546)
Indications for use	Protection of teeth and restorations from the forces of bruxism. Recovery from temporal mandibular disease (TMD) in which bruxism is a contributing factor.	For the prevention of chronic tension and temporal joint syndrome that is caused by chronic clenching of the posterior mandibular and maxillary teeth by the temporalis muscle.
Method of manufacture	Custom fabricated	Custom fabricated
Single patient, intraoral device	yes	yes
Material	Thermoplastic acrylic	Thermoplastic acrylic
Method of action/intended use.	An anterior bite stop that inhibits masticatory musculature.	An anterior bite stop that inhibits masticatory musculature.
Risk of material exposure	None	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2007

MCI-Myohealth Systems
C/O Mr. David Balding
Consultant and Authorized Contact
David Balding
26552 Tampico Place
Mission Viejo, California 92691

Re: K040315
Trade/Device Name: MCI-Myohealth Clenching Inhibitor
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQC
Dated: August 19, 2004
Received: August 23, 2004

Dear Mr. Balding:

This letter corrects our substantially equivalent letter of August 27, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

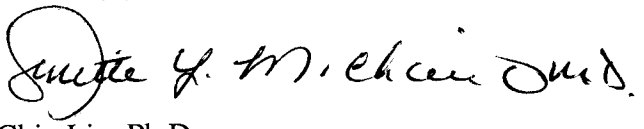
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040315

Indications for Use

510(k) Number (if known): K040315

Device Name: MCI-MyoHealth Clenching Inhibitor

Indications For Use:

1. **Protection of teeth and restorations from the forces of bruxism.**

2. **For the prevention of TMJ syndrome through reduction of trigeminally innervated muscular activity.**

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040315